Ref: Den 97-10

DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE

D1184B

Food and Drug Administration
Denver District Office
Building 20 - Denver Federal Center
P. O. Box 25087
Denver, Colorado 80225
TELEPHONE: 303-236-3000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

February 11, 1997

Mr. Jay E. Webb, Owner
Webb Livestock Company
3320 East 2620 South
St. George, Utah 84790

PURGED

Dear Mr. Webb:

An inspection of your company located in St.George, Utah, was conducted on April 19 and 20, 1996, by Food and Drug Administration (FDA) Consumer Safety Officer Sharon M. Harold, RN. As a result of this inspection, it is confirmed that a cow purchased and sold by you on or about March 8, 1996, and transported for slaughter for human food to was in violation of Section 402 (a)(2)(D) of the Federal Food, Drug, and Cosmetic Act (the Act).

USDA/FSIS analysis of tissues collected from that animal disclosed the presence of the drug Sulfamethazine in muscle tissue at ppm. A tolerance of 0.1 ppm has been established for residues of Sulfamethazine in the edible tissues of cattle [Title 21 Code of Federal Regulations Part 556.670 (21 CFR 556.670)]. The presence of this drug in edible tissue from this animal causes the food to be adulterated. Please note that this animal was part of a shipment of cows delivered by . There were two animals condemned as part of this shipment, one for epithelioma, and a second for sulfamethazine residue.

In addition, USDA has reported the finding of illegal residues in yet another cow sold by you and offered for slaughter for human food. A cow with backtag # from a shipment of cows shipped by you and received by on or about May 2, 1996, was found to have Sulfadimethoxine residues of ppm in the liver and ppm in the muscle. A tolerance of 0.1 ppm has been established for residues of Sulfadimethoxine

in the edible tissues of cattle (21 CFR 556.640). Copies of letters from USDA/FSIS notifying you of these residues are enclosed.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action such as seizure and/or injunction without further notice.

The violations listed above are not intended to be an all inclusive list. It is your responsibility to assure that your operations are in compliance with the law. As a dealer of animals, you are frequently the individual who introduces, or offers for introduction into interstate commerce, the adulterated animal. As such, you share the responsibility for violating the Federal Food, Drug and Cosmetic Act. To avoid future illegal residue violations you should take precautions such as:

1) implement a system to identify the animals you purchase with records to establish traceability to the source of the animal;

2) implement a system to determine from the source of the animal whether the animal has been medicated and with what drug(s); and;

3) if the animal has been medicated, implement a system to withhold the animal from slaughter for an appropriate period of time to deplete potentially hazardous residues of drugs from edible tissue. If you do not want to hold the medicated animal, then it should not be offered for human food, and it should be clearly identified and sold as a medicated animal.

You should notify this office in writing within 15 working days of the steps you have taken to bring your firm into compliance with the law. Your response should include each step being taken, that has been taken, or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the timeframe within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your response should be sent to Shelly L. Maifarth, Compliance Officer, Food and Drug Administration, P.O.Box 25087, Denver, Colorado 80225-0087.

Sincerely,

PURGED

Carole J. Wade

for Gary C. Dean
Director, Denver District

Enclosures:
1. 21 CFR 566.640 and 566.670
2. Section 402 (a)(2)(D) of the Federal Food, Drug, and Cosmetic Act
3. USDA Laboratory Report #
4. USDA/FSIS Letter of March 28, 1996
5. USDA Laboratory Report #
6. USDA/FSIS Letter dated May 29,1996, to
   regarding: Case Number

cc w/encl:

USDA/FSIS
Dr. Jerome Zimka, Area Supervisor
Dr. Ron Nelson, Assistant Area Supervisor
665 S. Broadway, Suite B
Boulder, CO 80303

Utah Department of Agriculture
Cary Peterson, Commissioner
350 North Redwood Road
Salt Lake City, UT 84116-3087

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